II. REMARKS

Formal Matters

Claims 1, 2, 4, 7-9, 11, 12, 16, and 17 are pending after entry of the amendments set forth herein.

Claims 1, 2, 4, 7-9, 11, 12, 16-18, and 20-28 were examined and were rejected.

Claims 1, 2, 8, 9, and 11 are amended. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim. No new matter is added by these amendments.

Claims 18 and 20-28 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Withdrawn rejections

Applicants note with gratitude that the rejection, made in the May 3, 2006 Office Action, of clams 1-14 and 16-28 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement, has been withdrawn.

PTO SB-08A form

Applicants respectfully request that the Examiner initial and return the PTO SB-08A forms submitted with the Information Disclosure Statements filed on September 7, 2005 and July 6, 2006 in this application, thereby indicating that the references cited therein have been reviewed and made of record.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1, 2, 4, 7-9, 11, 12, 16, 17, 20, and 25 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Claims 18, 21-24 and 26-28 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

Claims 1, 2, 4, 7-9, 11, 12, 16, 17, 20, and 25

The Office Action stated that this is a new matter rejection for the reasons of record in the Office Action mailed May 3, 2006. The May 3, 2006 Office Action stated that support for "Arc mRNA" and "ERK mRNA" cannot be found in the specification. Applicants respectfully traverse the rejection.

According to the MPEP §2163.07, amendments to an application which are supported in the original description are not new matter. Mere rephrasing of a passage does not constitute new matter. MPEP §2163.07. Furthermore, the subject matter of the claim need not be described literally (i.e., using the same terms) in order for the disclosure to satisfy the written description requirement. MPEP §2163(II)(A)(3)(a) and §2163.02. The burden is on the examiner to present evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. MPEP §2163(III)(A).

No new matter has been added by "Arc mRNA" and "ERK mRNA."

Applicants note that paragraph 0021 of the instant specification states that a "calcium-responsive gene product" refers to a protein and/or an mRNA whose level varies with the intracellular calcium concentration. Paragraph 0021 of the instant specification states that calcium-responsive gene products include a phospho-extracellular signal-regulated kinase (phospho-ERK or p-ERK) gene product. Paragraph 0052 of the instant specification states that other examples of calcium-responsive gene products are immediate early gene products such as c-Fos and Arc.

Paragraph 0021 of the instant specification states:

> The terms "**calcium-responsive gene product**," and "calcium-dependent gene product," as used interchangeably herein, **refer to a protein and/or an mRNA** whose level varies with the intracellular calcium ion concentration ($[Ca^{2+}_i]$). Calcium-responsive gene products include products of genes that include a calcium-responsive transcriptional regulatory element; calcium-binding proteins (e.g., calbindin); neuropeptide Y (NPY); an α-actinin II gene product; a phospho-extracellular signal-regulated kinase (phospho-ERK or p-ERK) gene product; immediate early response genes (e.g., c-Fos); and the like.

Specification, paragraph 0021, emphasis added.

Thus, paragraph 0021 makes it clear that the term "gene product" includes both mRNA and protein.

Paragraph 0021 of the instant specification states:

> The terms "calcium-responsive gene product," and "calcium-dependent gene product," as used interchangeably herein, refer to a protein and/or an mRNA whose level varies with the intracellular calcium ion concentration ($[Ca^{2+}_i]$). **Calcium-responsive gene products include** products of genes that include a calcium-responsive transcriptional regulatory element; calcium-binding proteins (e.g., calbindin); neuropeptide Y (NPY); an α-actinin II gene product; a phospho-extracellular signal-regulated kinase (**phospho-ERK or p-ERK) gene product**; immediate early response genes (e.g., c-Fos); and the like.

Specification, paragraph 0021, emphasis added.

Thus, paragraph 0021 lists ERK gene products. Since, as noted above, paragraph 0021 makes it clear that "gene product" includes mRNA and protein, paragraph 0021 provides written description support for "ERK mRNA."

Paragraph 0052 of the instant specification states:

> Other examples of **calcium-responsive gene products** that are suitable for detection using a method of the present invention is immediate early gene products such as c-Fos and **Arc**. Thus, in some embodiments, the method involves detecting a level of c-Fos protein in the hippocampus, e.g., in a granule cell of the dentate gyrus. As discussed in the Example, a reduced level of c-Fos in hippocampal neurons correlates with behavioral deficits, such as cognitive impairment, associated with AD. Thus, in some embodiments, the methods involve detecting a level of c-Fos protein and/or mRNA in a sample. In many embodiments, c-Fos levels are detected in a granule cell of the dentate gyrus. A level of c-Fos polypeptide is detected by employing immunological methods as described above, using antibody specific for c-Fos.

Specification, paragraph 0052, emphasis added.

Thus, paragraph 0052 lists Arc gene products. Since, as noted above, paragraph 0021 makes it clear that "gene product" includes mRNA and protein, paragraph 0052 provides written description support for "Arc mRNA."

In view of the above-noted description in the specification, those skilled in the art would recognize in the disclosure a description of "ERK mRNA" and "Arc mRNA." As such, the terms "ERK mRNA" and "Arc mRNA" do not add new matter. Accordingly, claims 1, 2, 4, 7-9, 11, 12, 16, 17, 20, and 25 are in compliance with the written description requirement of 35 U.S.C. §112, first paragraph.

Claims 18, 21-24, and 26-28

Claims 18, 21-24, and 26-28 are canceled without prejudice to renewal, thereby rendering this rejection of claims 18, 21-24, and 26-28 moot.

Conclusion as to the rejections under 35 U.S.C. §112, first paragraph

Applicants submit that the rejections of the claims discussed above under 35 U.S.C. §112, first paragraph, have been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejections.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1, 2, 4, 7-9, 11, 12, 16, and 17 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

Claims 2 and 9

The Office Action stated that claim 2 and claim 9 recite "non-human animal"; and stated that there is insufficient basis for this recitation.

Claims 2 and 9 are amended to recite "transgenic mouse model." Sufficient antecedent basis for such a recitation is provided in claims 1 and 8, from which claims 2 and 9, respectively, depend.

Claims 1, 2, 4, 7-9, 11, 12, 16, and 17

The Office Action stated that claims 1, 2, 4, 7-9, 11, 12, 16, and 17 recite "phospho-ERK mRNA"; and stated that mRNA is never phosphorylated, but the kinase is.

Claims 1 and 8 are amended to recite "an ERK mRNA," thereby adequately addressing this rejection.

Conclusion as to the rejections under 35 U.S.C. §112, second paragraph

Applicants submit that the rejection of claims 2 and 8, and the rejection of claims 1, 2, 4, 7-9, 11, 12, 16, and 17 under 35 U.S.C. §112, second paragraph, have been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejections.

III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCAL-280.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: July 30, 2007

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